

## REMARKS

Claims 1, 2, 4, 5, 7 and 19 stand rejected; while claims 6, 8-11 and 18 are objected to. Claim 1 has been amended to recite "CD8  $\alpha$ -chain" rather than "CD8  $\alpha$ -chain polypeptide." Claims 1 and 19 have been amended to recite that the encoded CD8  $\alpha$ -chain and the therapeutic molecule are separately expressed. These amendments find support throughout the originally-filed specification. Paragraph 0014, for example, provides that the CD8 polypeptide and the therapeutic molecule can be "encoded by separate expression vectors;" while paragraph 0106 describes "expression vectors" as generally including transcriptional and translational regulatory nucleic acid operably linked to the nucleic acid encoding the protein. Accordingly, the specification provides support for separate expression of the encoded CD8  $\alpha$ -chain and therapeutic molecule by separate transcriptional and translational regulatory nucleic acid operably linked to the nucleic acid encoding each protein. Accordingly, there is no issue of new matter.

Also, Claims 2 and 4, as well as claims 11, 18 and 19, have been amended to recite "said CD8  $\alpha$ -chain," in accordance with the claims from which they depend; while Claims 6 and 8 have been amended to remove improper dependencies. These amendments also raise no new matter issues.

Further, new claims 20-31 have been added. The new claims are based on previously pending claims 1, 2, 4-11, 18 and 19, with the addition that the independent claims specify that the CD8  $\alpha$ -chain is "not a fusion protein." This addition finds direct support in the originally-filed specification, e.g., at paragraph 0068, which provides that "[i]n a preferred embodiment the CD8  $\alpha$ -chain is not a fusion protein, ... ." Accordingly, the new claims are also free from any issues of new matter.

With respect to all amendments and new claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Applicants respectfully request that these amendments under 37 C.F.R. § 1.116 be entered by the Examiner. Applicants respectfully submit that the proposed amendments do not raise new

issues nor necessitate additional searches of the art. Rather, these amendments should allow for immediate favorable action by the Examiner.

### **Rejoinder of Withdrawn Claims**

Applicants thank the Examiner for the reminder that a reply to the final Office Action must include cancellation of the nonelected claims or other appropriate action. Action at page 2. With respect to the Office's statement that claims 12, 14 and 15 were "nonelected with traverse", however, Applicants respectfully point out that the election in response to the Election/Restriction Requirement of May 31, 2006, was made without traverse.

Moreover, as previously noted, Applicants made that election with the understanding that upon the finding of a product claim allowable, the withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim would be rejoined, in accordance with M.P.E.P. §821.04. Withdrawn process claims 12, 14 and 15 each depend, directly or indirectly, from product claim 1. Indeed, as the M.P.E.P. advises, these claims to the nonelected invention(s) were amended, in Applicants' prior response, to require the limitations of the elected claimed invention, thereby retaining the right to rejoinder. *Id.*

As such, Applicants respectfully request consideration and rejoinder of withdrawn process claims 12, 14 and 15, upon the finding of amended product claim 1 allowable. In addition, Applicants reserve the right to pursue the subject matter of the non-elected inventions at a later date, for example, in continuing or divisional applications.

### **Claim objections**

Claims 6, 8-11 and 18 were objected to as being in improper multiple dependent form. Action at page 3. Further, claims 2 and 4 were objected to for reciting "said CD8 polypeptide" rather than "said CD8 α-chain polypeptide" in accordance with the independent claim from which they depend. *Id.*

Applicants thank the Examiner for pointing out these informalities. Applicants have amended claims 6 and 8 to remove improper dependencies, thereby also correcting claims 9-11

and 18, which depend from amended claim 8. Further, as noted above, claim 1 now recites “a CD8  $\alpha$ -chain”, while claims 2 and 4 now recite “said CD8  $\alpha$ -chain”, thereby obviating any issues of lack of antecedent basis.

In light of these amendments, Applicants respectfully request reconsideration and withdrawal of the claim objections.

### **Withdrawn Rejections**

Applicants acknowledge the withdrawal of claim rejections based on 35 USC §§ 112 and 101, and thank the Examiner for same.

### **Aruffo Rejections**

#### ***Claim Rejections under 35 USC § 102(b)***

While the rejection of claim 5 is withdrawn, claims 1 and 2 remain rejected, and claim 19 is newly rejected, as allegedly being anticipated by US Patent No. 5,540,926 to Aruffo *et al.*, further evidenced by WO 04/042346 to Wohlgemuth *et al.* Action at pages 4-5. According to the Office, Applicants’ prior arguments that the invention is not a fusion construct are not persuasive because the claims did not preclude a fusion construct. Action at page 5.

Without acquiescing to the Office’s contentions in any way, Applicants have amended claims 1 and 19 to recite that the encoded CD8  $\alpha$ -chain and the therapeutic molecule are separately expressed, as indicated above. Claim 2 is likewise amended, as depending from amended claim 1. Such separate expression necessarily precludes the production of a fusion between the CD8  $\alpha$ -chain and the therapeutic polypeptide. That is, separate expressions produce distinct transcripts for each of the CD8 molecule and the therapeutic molecule, which then are translated into separate protein molecules, rather than a fusion construct. As Aruffo teaches only fusion constructs, however, Applicants respectfully submit that Aruffo cannot anticipate the claims as currently amended.

Accordingly, Applicants respectfully and earnestly request reconsideration and withdrawal of these 102(b) rejections directed at claims 1, 2, and 19.

***Claim Rejections under 35 USC § 103(a)***

Similarly, the rejection of claim 5 is withdrawn, while claims 1 and 2 remain rejected, and claim 19 is newly rejected, as allegedly being obvious in view of US Patent No. 5,540,926 to Aruffo *et al.* as further evidenced by WO 04/042346 to Wohlgenuth *et al.*, in combination with either US Patent No. 6,193,980 to Efsthathiou, *et al.* or US Patent No. 6,509,150 to Salvetti, *et al.* or US patent No. 6,207,456 to Baru, *et al.* Action at pages 5-10. According to the Office, Applicants' prior arguments that Aruffo provides no motivation for anything other than a fusion protein is not persuasive, since the claims did not preclude fusion constructs. Action at pages 7, 8 and 10. The Office specifies that "without such specific language removing fusion constructs in the claims, the claims are necessarily obvious." *Id.*

Without acquiescing to the Office's contentions in any way, Applicants have amended claims 1 and 19 as noted above to recite that the encoded CD8  $\alpha$ -chain and the therapeutic molecule are separately expressed, and claim 2 is amended accordingly as depending from claim 1. Thus, as suggested by the Office and as discussed above, Applicants have included "specific language removing fusion constructs from the claims." *Id.* As stated before, Aruffo fails to teach or suggest anything other than fusion proteins and neither Efsthathiou, Salvetti, Baru nor Wohlgenuth remedy this deficiency. Accordingly, Applicants respectfully submit that the currently amended claims cannot be rendered obvious in view of the cited references.

Applicants thus respectfully and earnestly request reconsideration and withdrawal of these 103(a) rejections directed at claims 1, 2, and 19.

**Bonyhadi Rejections**

***Claim Rejections under 35 USC § 102(b)***

Claims 1, 4 and 5 remain rejected, and claim 19 is newly rejected, as allegedly being anticipated by Bonyhadi *et al.* (1997) J. Virol., 71(6): 4707-16. Action at pages 10-12. According to the Office, Applicants' prior arguments that Bonyhadi only describes a single transcript encoding both the CD8-alpha molecule and the therapeutic molecule are not persuasive because the claims did not require distinct transcripts for the encoded molecules. Action at pages 11-12.

Without acquiescing to the Office's contentions in any way, Applicants respectfully submit that the current amendments to claims 1 and 19 clearly require distinct transcripts for the encoded CD8 and therapeutic molecules. That is, as the amended claims specify separate expression of the encoded CD8  $\alpha$ -chain and therapeutic molecule, it follows that separate and distinct transcripts are produced for each, as discussed above. Claims 4 and 5 are likewise amended, as depending (directly or indirectly) from amended claim 1.

Conversely, as stated before, Bonyhadi only describes a single transcript encoding both the CD8-alpha molecule and the therapeutic molecule and nowhere teaches their separate expression. Accordingly, Applicants respectfully submit that Bonyhadi cannot anticipate the claims as currently amended.

Applicants thus respectfully and earnestly request reconsideration and withdrawal of these 102(b) rejections directed at claims 1, 4, 5 and 19.

***Claim Rejections under 35 USC § 103(a)***

Similarly, claims 1, 4, 5 and 7 remain rejected, and claim 19 is newly rejected, as allegedly being obvious in view of by Bonyhadi *et al.* (1997) J. Virol., 71(6): 4707-16, in combination with Zimmer, *et al.* (1999) Molecular Medicine 5(4): 244-53. Action at pages 12-14. According to the Office, Applicants' prior arguments that Bonyhadi only teaches a single transcript for both the CD8-alpha molecule and the therapeutic molecule are not persuasive as there is no "mechanistic description" in the claims requiring separate transcripts. Action at pages 13-14.

Without acquiescing to the Office's contentions in any way, Applicants have amended claims 1 and 19 as noted above to include such a "mechanistic description" requiring separate transcripts. That is, claims 1 and 19 recite that the encoded CD8  $\alpha$ -chain and the therapeutic molecule are separately expressed, and claims 4, 5 and 7 are likewise amended, as depending (directly or indirectly) from amended claim 1.

Conversely, as stated before, Bonyhadi fails to teach or suggest anything other than a single transcript containing both the CD8-alpha molecule and the therapeutic molecule. Zimmer does nothing remedy this deficiency. Accordingly, Applicants respectfully submit that the currently amended claims cannot be rendered obvious in light of the cited references.

Applicants thus respectfully and earnestly request reconsideration and withdrawal of these 103(a) rejections directed at claims 1, 4, 5, 7 and 19.

#### **Novelty and Non-obviousness of the New Claims**

Applicants wish also to point out the novelty and nonobviousness of new claims 20-31 in view of the Aruffo and Bonyhadi references, either alone or in combination with other cited references.

##### ***The New Claims are Novel over Aruffo (and Wohlgemuth)***

As indicated above, the new claims specify that the CD8  $\alpha$ -chain is “not a fusion protein”. With respect to the Aruffo novelty rejections discussed above, the Office alleged that Applicants’ prior arguments were not persuasive because the claims did not preclude a fusion construct. Action at page 5. Applicants respectfully submit that the new claims clearly preclude fusion proteins and, as Aruffo teaches only fusion constructs, Aruffo could not anticipate these claims.

##### ***The New Claims are NonObvious over Aruffo (with Efstathiou, Salvetti or Barr)***

Similarly, as new claims 20-31 include specific language excluding fusion proteins, they cannot be rendered obvious by Aruffo in combination with any of Efstathiou, Salvetti, Baru or Wohlgemuth. As stated before, Aruffo fails to teach or suggest anything other than fusion proteins and neither Efstathiou, Salvetti, Baru nor Wohlgemuth remedy this deficiency. Thus, Aruffo, in combination with any of Efstathiou, Salvetti, Baru or Wohlgemuth, could not render obvious the new claims that specifically preclude fusion constructs.

##### ***The New Claims are Novel over Bonyhadi***

With respect to the Bonyhadi novelty rejections discussed above, the Office found Applicants’ prior arguments unpersuasive as the claims allegedly did not require distinct transcripts for the encoded CD8- $\alpha$  and therapeutic molecules. Action at pages 11-12. New claims 20-31, however, explicitly preclude fusion proteins, and thus also a single transcript encoding such fusions. As Bonyhadi only describes a single transcript encoding both the CD8- $\alpha$  molecule and the therapeutic molecule, it follows that Bonyhadi could not anticipate the new claims.

***The New Claims are Nonobvious over Bonyhadi (in combination with Zimmer)***

Finally, the Office looked for a “mechanistic description” requiring separate transcripts to distinguish Applicants’ claims from Bonyhadi in combination with Zimmer. Action at pages 13-14. New claims 20-31 provide such a description by specifically precluding a fusion protein, which would be translated from a single rather than separate transcripts. As Bonyhadi/Zimmer, in contrast, fail to teach or suggest anything other than a single transcript containing both the encoded molecules, Applicants respectfully submit that Bonyhadi in combination with Zimmer could not render the new claims obvious.

### CONCLUSION

Applicants respectfully submit that the invention of the amended and new claims is neither anticipated nor rendered obvious in view of the art references cited against this application. Applicants thus respectfully request entry of these amendments and reconsideration of the application. Applicants earnestly and respectfully request timely allowance of product claims 1, 2, 4-11 and 18-31, as well as rejoinder of withdrawn process claims 12, 14 and 15.

If a telephone call will help expedite any aspect of the prosecution of the instant application, Applicants encourage the Examiner to contact the undersigned by telephone at (415) 568-2257 or by fax at (415) 568-2260.

Respectfully submitted,  
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